TIDI PRODUCTS
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Certified to ISO 9001:2000, EN/ISO 13485:2003, European CE Mark

K100800

510(k) Summary
TIDI® Facemask

To: Whom it may concern

Date: May 21, 2010

JUN 14 2010

Submitter/ Contact - Name and Address

Dion J. Brandt
Quality Manager
TIDI Products, LLC
570 Enterprise Drive
Neenah WI 54956
Telephone: (920) 751-4386
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FDA Registration Number: 2182318

Device Details:

Name of the Device
Trade Name: *TIDI® Facemask*
Or Customer Specific trade name
Model: Procedure
Common Name: Surgical Mask
Classification Name: Mask, Surgical
Product Code: FXX
Regulation Number: 878.4040

Equivalent Legally Marketed Device:

Predicate Devices	**510 K Number:**
1) TIDI® Face mask Model 9010 and 9020	K092580
2) A.R. Medicom Non-Sterile Surgical Mask	K051291

DESCRIPTION OF THE DEVICE:

The *TIDI® Facemask* are pleated multi-ply design which are supplied non sterile. The outer layers are made of 100% spun-bound polypropylene (SBPP). The filter media is composed of 100% melt-blown polypropylene (MBPP). The inner layer is made of 100% SBPP. The nosepieces are made of aluminum, and can be supplied with an anti fog strip made of polyester urethane foam. All materials used in the construction of the mask are being used in currently marketed devices. The face mask covers the nose and mouth, and is secured to the face using ear loops.

INTENDED USE:

The *TIDI® Facemask* intended use is: Surgical mask are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, body fluids and particulate material.

Device and Predicate Device Technical Characteristics Summary

TIDI® Facemask has the same intended use and is technologically similar to the predicate device. The *TIDI® Facemask* and the predicate device are pleated, multi-ply, design and consist of non-woven barrier materials selected and arranged in such a manner as to provide optimal breathability and particulate filtration. Table 5.1 compares the *TIDI® Facemask* technical characteristics to the predicate devices

Table 5.1 Device and Predicate Device Technical Characteristics Summary

Description	TIDI® Facemask Model: Procedure	Predicate Device TIDI® Facemask Model 9010 and 9020 K092580	Predicate Device A.R. Medicom Non-Sterile Surgical Mask K051291
Material Composition Type of fabric:			
Outer Layer	Polypropylene Spun-bond	Polypropylene Spun-bond	Polypropylene Spun-bond
Filter Media	Melt-blown polypropylene	Melt-blown polypropylene	Melt-blown polypropylene
Inner Layer	Polypropylene Spun-bond	Polypropylene Spun-bond	Polypropylene Spun-bond
Other Materials:			
Nose Piece:	Aluminum	Aluminum	Aluminum
Ear Attachment:	Elastic	Elastic	Elastic
Anti-Fog	Polyester Urethane foam	Polyester Urethane foam	none
The difference of the anti fog material is the polyester urethane foam. The polyester foam material has been used in medical application on facemask for an anti-fog strip without any toxicity or biological compatibility issues. It has been proven to be non-toxic, non-sensitizing, and non-irritating.			
Design Features:	Ear Loop Fluid Resistant	Ear Loop Fluid Resistant	Ear Loop Fluid Resistant
Mask Style:	Flat Pleated	Flat Pleated	Flat Pleated
Sterile:	No	No	No
Single Use:	Yes	Yes	Yes

Non-Clinical Performance Data

TIDI® Facemask meet the requirements of ASTM F-2100-07, Standard Specification for performance of Materials Used in Medical Face Masks. The testing required for this specification are, ASTM 1862-07, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

ASTM F 2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres.

ASTM 2101-07 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.

16 CFR Part 1610 Standard for the Flammability of Clothing Textiles.

Conclusion:

The conclusions drawn from the intended use, technical characteristics and nonclinical testing demonstrate that the *TIDI® Facemask* is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dion Brandt
Quality Manager
TIDI Products, LLC
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Neenah, Wisconsin 54956

JUN 14 2010

Re: K100800
Trade/Device Name: TIDI Facemask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: March 18, 2010
Received: March 22, 2010

Dear Mr. Brandt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Medical Devices

Indications for Use Form

Indications for Use

510(K) Number (if Known): _K100800_____

Device Name: TIDI® Facemask - Model -Procedure

Surgical mask are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, body fluids and particulate material.

Prescription use_____ AND/OR Over- The Counter Use ___X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100800